

Amendment and Response
First Names Inventor: Zoerb, Hans
Serial No.: 10/559,504
Filed: May 22, 2006
Attorney Docket No.: CGL03/0204US01
Title: BEVERAGE ADDITIVE MIXTURE OF TREHALOSE AND PROTEIN

REMARKS

The following remarks are made in response to the Non-Final Office Action mailed January 7, 2009. Claims 1-22 were rejected. With this response, claims 1, 2, 4-6, 9-11, 14-16 and 19-22 have been amended, new claims 23-29 have been added and claims 3, 7-8, 12-13 and 17-18 have been cancelled. Thus, claims 1, 2, 4-6, 9-11, 14-16 and 19-29 remain pending in the application and are presented for reconsideration and allowance.

Claim Rejections under 35 U.S.C. § 112

The Examiner has rejected claims 1, 6, 11, 16 and their dependents under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. The Examiner states that it is unclear as to what is encompassed by the phrase "normally bitter/cardboard tasting protein." The Applicant respectfully disagrees with the Examiner and submits that this term is commonly used in the art as evidenced by the attached copy of Whetstone et al., *J. Dairy Science* 88:3826-3839, 2005 (see, Table 2). In the interest of advancing prosecution of this matter, however, claims 3, 7-8, 12-13 and 17-18 have been cancelled and claims 1, 2, 4-6, 9-11, 14-16 and 19-22 have been amended to replace the phrase "normally bitter/cardboard tasting protein" with "native whey protein or native casein protein." One of skill in the art would clearly understand what a native whey protein or native casein protein is. Therefore, claims 1, 6, 11, 16 and their dependents are not indefinite and the applicant respectfully requests reconsideration and allowance of these claims.

Claim Rejections under 35 U.S.C. § 103

The Examiner has rejected claims 1, 3-6, 8-11, 13-16 and 18-22 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,919,668 to Mandai (hereinafter

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"Mandai") in view of U.S. Patent No. 6,703,051 to Bates (hereinafter "Bates") as evidenced by Soypeptidesabsorb NPL, Soybeanpeptideamino NPL, Soypeptidehydrolyzate NPL and ScienceDirectPeptides NPL. The Examiner states that Mandai teaches mixing a soybean peptide in 40% solution with trehalose followed by drying the mixture at 50C, which would substantially dehydrate it. The Examiner then states that Mandai teaches adding the mixture to flavored nutritional beverages such as parenteral liquid foods and that because trehalose is mixed with the soybean peptide in 40% solution, it is considered to be substantially distributed throughout the soybean peptide in 40% solution. The Examiner further states that trehalose has a favorable taste masking effect and taste improving effect and that it would have been obvious to one of ordinary skill in the art at the time of the invention to add trehalose in amounts that would mask the taste of the soybean peptide in 40% solution in order to allow the beverage to which it is being added to retain its original taste. The applicant respectfully disagrees.

Claims 1, 3-6, 8-11, 13-16 and 18-22 have been amended and claims 23-29 have been drafted to incorporate the term "native protein" which is fairly based on the specification, for example, at page 7, lines 20-22 of the application as originally filed. The concept of the invention is generally discussed throughout the specification and is shown in the examples (where trehalose is mixed with newly produced, native proteins).

The applicant submits that Mandai describes the production and use of non-reducing saccharides. In one case, as described in Example 13 of Mandai, trehalose was added to a solution of rehydrated soybean peptide and then dried. The product had improved taste and flavor and could be used in various foods. HINUTE™ Soy Peptides (erroneously called Himute in Example 13 of Mandai) are a series of soy peptides (-S, -D1 and -DC6) available from Fuji Oil Company. Each of these products is sold in powder form, as shown on the attached information sheet. The powdered

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form is shown by a moisture content of < 7% as well as product packaging in a multi-layer paper bag.

As described in the background (see page 1, lines 25-28 of the present specification), when a protein is heated above a given temperature and dehydrated, it can easily become partially denatured resulting in changes to native structure and loss of certain functional properties. For example, spray drying is a common form of drying soy proteins (peptides) and this processing denatures and degrades the protein due to elevated temperature and pressure conditions. As HINUTE-S™ is a dried product (i.e. a non-native protein), Mandai would have been required to rehydrate the soy protein into a 40% solution prior to the addition of trehalose. Therefore, the soy proteins used in Mandai have already been damaged by a dehydration process and remain damaged even after rehydration.

In contrast, the method of the current claims adds trehalose to a native protein mixture prior to any dehydration of the proteins. The Applicant has found that the addition of trehalose to a protein containing mixture prior to dehydration protects the proteins, and the resulting dry (and later rehydrated) protein is substantially undamaged. The use of trehalose has a beneficial impact on structure and functionality as well as taste (page 6, last paragraph to page 7, last paragraph of the present specification).

Accordingly, trehalose will help mask native whey protein or native casein protein off flavors, including off-flavors that may be described as bitter/cardboard-tasting, even after the protein has been dried. As protein denaturation has already occurred in Mandai, the trehalose will be less effective than when added prior to drying. Adding trehalose to proteins prior to drying reduces the denaturation of the proteins and the concomitant structure changes, as well as reducing the production of bitter and other off flavors. Mandai makes no statements relating to the fact that trehalose will protect

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proteins (or peptides) during heat treatments prior to and during the drying process, and does not discuss or suggest adding trehalose to native proteins.

The Examiner further states that while Mandai does not teach the use of soy protein, soy protein and soy peptides are known to both be a major source of plant proteins in the human diet, citing ScienceDirect, Peptides as support. The Examiner also states that Bates discloses that soy protein is known to be used in nutritional beverages. The Examiner then reasons that one of ordinary skill in the art at the time of the invention would have been motivated to substitute soy peptide for soy protein in order to provide a nutritional beverage that contains all of the amino acids that soy protein contains even though soy peptides are more desireable for drinks such as sports drinks because they are known to absorb more easily into muscles per Soypeptideabsorb NPL, because consumers desiring a complete source of amino acids in their beverages would desire soy protein over soy peptide and thus one of ordinary skill in the art would have been motivated to substitute the soy protein disclosed by Bates for the soy peptide taught in Mandai in order to make the invention of Mandai attractive to a wider group of consumers.

As has been previously shown, however, the protein denaturation of Mandai would apply to soy peptide as well as soy protein and like Mandai, neither Bates nor the cited references of Soypeptidesabsorb NPL, Soybeanpeptideamino NPL, Soypeptidehydrolyzate NPL and ScienceDirectPeptides NPL discuss or suggest adding trehalose to native proteins.

Therefore, claims 1, 3-6, 8-11, 13-16 and 18-22 are patentable over Mandai in view of Bates as evidenced by Soypeptidesabsorb NPL, Soybeanpeptideamino NPL, Soypeptidehydrolyzate NPL and ScienceDirectPeptides NPL and the applicant respectfully requests reconsideration and allowance of these claims.

Examiner has also rejected claims 2, 7, 12 and 17 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,919,668 to Mandai (hereinafter "Mandai") in

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view of U.S. Patent No. 6,106,874 to Liebrecht (hereinafter "Liebrecht") as evidenced by whey vs. soy protein NPL. The Examiner again states that Mandai teaches mixing a soybean peptide in 40% solution with trehalose followed by drying the mixture at 50C, which would substantially dehydrate it. The Examiner further states that Mandai teaches adding the mixture to flavored nutritional beverages such as parenteral liquid foods and that because trehalose is mixed with the soybean peptide in 40% solution, it is considered to be substantially distributed throughout the soybean peptide in 40% solution. The Examiner then states that Mandai does not teach the use of whey protein but that whey protein and soy peptides are known to be an important source of proteins in the human diet, citing Liebrecht as teaching the use of whey proteins in the creation of a nutritional beverage; the whey proteins being known to be very high in biological activity and thus highly desired by athletes. According to the Examiner, one of ordinary skill in the art at the time of the invention would have been motivated to substitute whey protein for soy peptide in order to produce a beverage that is very high in biological value. The Applicant respectfully disagrees.

Claims 7, 12 and 17 have been cancelled. Claim 2 has been amended to incorporate the term "native protein" which is fairly based on the specification, for example, at page 7, lines 20-22 of the application as originally filed. The concept of the invention is generally discussed throughout the specification and is shown in the examples (where trehalose is mixed with newly produced, native proteins).

As previously submitted, Mandai describes the production and use of non-reducing saccharides such as HINUTETM Soy Peptides sold in powder form. Again, as described in the background (see page 1, lines 25-28 of the present specification), when a protein is heated above a given temperature and dehydrated, it can easily become partially denatured resulting in changes to native structure and loss of certain functional properties. For example, spray drying is a common form of drying soy proteins (peptides) and this processing denatures and degrades the protein due to

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elevated temperature and pressure conditions. As HINUTE-S™ is a dried product (i.e. a non-native protein), Mandai would have been required to rehydrate the soy protein into a 40% solution prior to the addition of trehalose. Therefore, the soy proteins used in Mandai have already been damaged by a dehydration process and remain damaged even after rehydration. This is in contrast to the method of the current claims where trehalose is added to a native protein mixture prior to any dehydration of the proteins. The Applicant has found that the addition of trehalose to a protein containing mixture prior to dehydration protects the proteins, and the resulting dry (and later rehydrated) protein is substantially undamaged. The use of trehalose has a beneficial impact on structure and functionality as well as taste (page 6, last paragraph to page 7, last paragraph of the present specification).

Because protein denaturation has already occurred in Mandai, the trehalose will be less effective than when added prior to drying. Adding trehalose to proteins prior to drying reduces the denaturation of the proteins and the concomitant structure changes, as well as reducing the production of bitter and other off flavors. Further, Mandai makes no statements relating to the fact that trehalose will protect proteins (or peptides) during heat treatments prior to and during the drying process, and does not discuss or suggest adding trehalose to native proteins.

Therefore, claims 2 is patentable over over Mandai in view of Liebrecht as evidenced by whey vs. soy protein NPL and the applicant respectfully requests reconsideration and allowance of these claims.

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Conclusion

In view of the above, Applicant respectfully submits that pending claims 1, 2, 4-6, 9-11, 14-16 and 19-29 are in form for allowance and are not taught or suggested by the cited references. Therefore, reconsideration and withdrawal of the rejections and allowance of claims 1, 2, 4-6, 9-11, 14-16 and 19-29 are respectfully requested.

No fees are required under 37 CFR 1.16(h)(i), however, the commissioner is authorized to charge any fees or credit any overpayment to Deposit Account No. 50-2342.

The Examiner is invited to contact the Applicant's representative at the below-listed telephone number to facilitate prosecution of this application.

Any inquiry regarding this Amendment and Response should be directed to Gretchen Skarohlid at Telephone No. (942) 742-2571. In addition, all correspondence should continue to be directed to the following address:

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Respectfully Submitted,

Date: July 7, 2009

/Gretchen Pesek Skarohlid/

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